

I. REMARKS

A. Status of Claims

Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94, and 96-98 are pending in this Application. The following claims have been cancelled from this Application: 1-3, 5-6, 10, 12, 16-33, 34, 37-39, 43-58, 61-70, and 95.

Claim 14 is amended herein to correct a minor matter of form. Claims 4, 73 and 74 are amended herein to particularly describe the type of polyvinyl alcohol polymer useful in the invention and to add the polymer vinylpyrrolidone/vinylimidazole copolymer as one of the preferred water soluble polymers useful in Applicants' claimed methods. Support for the amendments made to Claims 4, 73 and 74 is found in the Table which appears at pages 15 and 16 of the specification (WO 00/67694).

B. Extension of Time

Accompanying this Preliminary Amendment is a Petition for Extension of Time (PTO/SB/22) for a 3-month extension of time as well as the required fee.

II. THE SECTION 103(a) REJECTION

In the Advisory Action dated 11/02/2009, Examiner states that Applicants' previous arguments do NOT place the application in condition for allowance because Applicants' arguments that the Coffee reference does not read on a rapid-dissolution oral dosage form, but rather a wound dressing which is bioresorbable or biodegradable and which does not rapidly dissolve upon contact with aqueous liquids and that there is no disclosure in Coffee which teaches one skilled in the art anything about the preparation of a rapid dissolution solid oral dosage form are refuted by the Coffee reference.

Examiner points to the Coffee reference at Page 31 which teaches a "method embodying a production process to form fibrils or particles comprising a biologically active ingredient and/or fibrils or microcapsules having a core of biologically active ingredient which may themselves be encapsulated in conventional orally ingestible

capsules, enabling, especially in the case of microcapsules, good control over the release of the active material."

It is respectfully contended that the disclosure of the Coffee fails to refute Applicants' arguments and that as would be recognized by one skilled in this art, the "good control" described by Coffee at page 31 of the reference refers to a product which would have a "controlled release" profile rather than a rapid-release" profile.

Attached hereto and incorporated herein, is the Declaration of Michael D. Triplett Ph.D. who is "one skilled in this art". Dr. Triplett states that in his opinion, the term "good control" used by the Coffee reference does not refer to a rapid release pharmaceutical product but would be understood by a skilled pharmaceutical formulator as referring to a "controlled release" product. His opinion is based on his knowledge of the qualities and uses of the polymers used in the wound dressings of the Coffee invention. These polymers, e.g., PLA and PLG are known to be useful in the preparation of controlled release pharmaceutical products.

As supported by the Declaration of Triplett, the polymers used in the invention of the Coffee reference are polymers which are well known to be useful in the preparation of sustained (controlled) release oral dosage forms. Assuming the skilled artisan was motivated to further research by the disclosure of Coffee, the logical direction would be in the area of sustained or controlled release.

The Coffee reference standing alone, fails to render the presently claimed invention obvious within the meaning of 35 USC §103(a); further, one skilled in this art would not have combined the teachings of Coffee with the teachings of Liu and Murray because the Coffee reference fails to provide any direction or teaching that would lead the skilled artisan to the preparation of a rapid-release tablet. The Coffee reference does teach the use of polymers which are known to be used in the preparation of controlled release tablets and that is the direction that the Coffee reference points the skilled artisan.

III. CONCLUSION

Based on the amendments, Declaration of Triplett and arguments made herein, it is respectfully asserted that Examiner's rejection of the claims under 35 USC §103(a) has been overcome and that this Application is in condition for allowance. Examiner is respectfully requested to withdraw all rejections and to issue a Notice of Allowance. If there are any questions regarding these amendments and remarks, Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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